# UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA, TAMPA DIVISION

PHARMASTEM THERAPEUTICS, INC., a Delaware corporation,

Plaintiff,

CASE NO. 8:04-CV-1740-T-30TGW

VS.

CRYO-CELL INTERNATIONAL, INC., a Delaware corporation, and BRUCE ZAFRAN, M.D., an individual,

Defendants.

CRYO-CELL INTERNATIONAL, INC., a Delaware corporation, and BRUCE ZAFRAN, M.D., an individual,

Counter-Claimants,

VS.

PHARMASTEM THERAPEUTICS, INC., a Delaware corporation, and NICHOLAS DIDIER, an individual,

Counter-Defendants.

#### **DEFENDANTS' JOINT ANSWER AND COUNTERCLAIM**

For their answer to Plaintiff PharmaStem Therapeutics, Inc.'s ("Plaintiff") Complaint, Defendants Cryo-Cell International, Inc. ("Cryo-Cell") and Bruce Zafran ("Zafran") (collectively, "Defendants") deny each and every matter, statement and thing alleged in Plaintiff's Complaint except as specifically admitted, qualifiedly admitted or explained herein, and further alleges as follows:

#### **Answer to Averments Regarding "Parties"**

- 1. Defendants lack knowledge or information sufficient to form a belief as to the truth of the averments contained in Paragraph 1, and on that basis deny each and every averment contained therein.
  - 2. Defendants admit the averments contained in Paragraph 2.
  - 3. Defendants admit the averments contained in Paragraph 3.

# Answer to Averments Regarding "Jurisdiction and Venue"

- 4. Defendants admit that the First Cause of Action and Second Cause of Action purport to be for patent infringement arising under 35 U.S.C. § 1 et seq, and that this Court has jurisdiction pursuant to 38 U.S.C. §§ 1331 and 1338. Except as expressly admitted, Defendants deny each and every averment contained in Paragraph 4.
  - 5. Defendants deny each and every averment contained in Paragraph 5.

#### **Answer to Averments Regarding Plaintiff's Patents**

- 6. Defendants admit that, on its face, Exhibit A attached to the Complaint purports to be a copy of U.S. Patent No. 6,461,645 B1 ("the '645 Patent") to which Defendants refer for a complete statement of its contents. Except as expressly admitted, Defendants deny each and every averment contained in Paragraph 6.
- 7. Defendants admit that, on its face, Exhibit B attached to the Complaint purports to be a copy of U.S. Patent No. 6,569,427 B1 ("the '427 Patent") to which Defendants refer for a complete statement of its contents. Except as expressly admitted, Defendants deny each and every averment contained in Paragraph 7.

8. Answering Paragraph 8, Defendants incorporate by reference as though fully set forth herein its responses to Paragraphs 6 and 7 of the Complaint. Except as expressly admitted, Defendants deny each and every averment contained in Paragraph 8.

### **Answer to Averments Regarding "Patent Infringement"**

- 9. Cryo-Cell admits that it provides expectant parents and physicians with collection kits to facilitate collection of blood from the umbilical cord of newborn babies. Cryo-Cell also admits that it collects certain fees for Cryo-Cell's services. Defendants deny the remaining averments contained in Paragraph 9.
- 10. Zafran admits that he has drawn blood from the umbilical cord of the children of his patients and that Cryo-Cell has processed and cryopreserved such blood for storage. Defendants deny the remaining averments contained in Paragraph 10.

# ANSWER TO "FIRST CAUSE OF ACTION" (For "Infringement of the '645 Patent")

- 11. Answering Paragraph 11, Defendants incorporate by reference, as though fully set forth herein, each and every response to Paragraphs 1 through 10 of the Complaint.
  - 12. Defendants deny each and every averment contained in Paragraph 12.
  - 13. Defendants deny each and every averment contained in Paragraph 13.
  - 14. Defendants deny each and every averment contained in Paragraph 14.

# ANSWER TO "SECOND CAUSE OF ACTION" (For "Infringement of the '427 Patent")

- 15. Answering Paragraph 15, Defendants incorporate by reference, as though fully set forth herein, each and every response to Paragraphs 1 through 14 of the Complaint.
  - 16. Defendants deny each and every averment contained in Paragraph 16.
  - Defendants deny each and every averment contained in Paragraph 17. 17.

18. Defendants deny each and every averment contained in Paragraph 18.

#### **ANSWER TO "PRAYER FOR RELIEF"**

19. Defendants deny each and every averment contained in the "Prayer for Relief" and pray that Plaintiff take nothing for each and every cause of action averred in the Complaint; that judgment on the Complaint, and each and every claim for relief therein, be entered in favor of Defendants and against Plaintiff; that Defendants be awarded Defendants' costs, including attorneys' fees, incurred in connection with this litigation; and for further relief as this Court deems just and proper.

#### **AFFIRMATIVE DEFENSES**

Defendants hereby assert the following affirmative defenses to the Complaint and each and every claim for relief set forth in the Complaint:

#### <u>First Affirmative Defense</u> (Failure to State a Claim)

20. The Complaint and each claim for relief contained therein fails to state a claim against Defendants upon which relief can be granted.

# **Second Affirmative Defense** (Non-Infringement)

21. Defendants did not infringe, contribute to the infringement, or induce infringement of any claim of the '645 Patent or the '427 Patent.

# Third Affirmative Defense (Invalidity)

22. The '645 Patent, the '427 Patent, and each and every claim contained in the '645 Patent and the '427 Patent are invalid for failure to meet the requirements specified in Part II of Title 35 U.S.C. including without limitation Sections 102, 103 and 112.

# **Fourth Affirmative Defense** (Prosecution History Estoppel)

23. Plaintiff is barred from presenting or seeking an interpretation of the claims necessary to find infringement of the '645 Patent or the '427 Patent by the manufacture, use, or sale of any Defendants' products, processes, or activities, either literally or under the Doctrine of Equivalents, by virtue of representations and concessions made to the United States Patent and Trademark Office ("PTO") during the prosecution of the applications that matured into the '645 Patent and the '427 Patent and to the District Court of Delaware.

### Fifth Affirmative Defense (Patent Misuse)

24. The '645 Patent, the '427 Patent, and each and every claim contained in the '645 Patent and the '427 Patent are unenforceable based upon patent misuse.

# **Sixth Affirmative Defense** (Incorrect Inventor(s))

- The '645 Patent, the '427 Patent, and each and every claim contained in the '645 25. Patent and the '427 Patent are unenforceable because Plaintiff failed to name the correct inventor(s) to the '645 Patent and the '427 Patent with intent to deceive the PTO to obtain issuance of the patents.
- 26 On information and belief, Pablo Rubinstein ("Rubinstein") made an inventive contribution to the claimed subject matter of the '645 Patent and the '427 Patent, to the extent the '645 Patent and the '427 Patent disclose and claim a patentable invention.
- 27. Additionally, on information and belief, Edward A. Boyse, a named inventor of the '645 Patent and the '427 Patent, is not an actual inventor of the '645 Patent or the '427 Patent to the extent the patents disclose and claim a patentable invention.

# **Seventh Affirmative Defense** (Inequitable Conduct)

- 28. The '645 Patent is unenforceable for inequitable conduct because the named inventors and/or the prosecuting attorney(s) of the patent withheld material information from the PTO with intent to deceive the PTO to obtain issuance of the '645 Patent and the '427 Patent.
- 29. Under 37 C.F.R. § 1.56, the named inventors and/or the prosecuting attorney(s) were required to disclose all information known to be material to patentability of the '645 Patent during the prosecution of such patent. Information material to patentability includes any information that refutes, or is inconsistent with, a position Plaintiff takes in asserting an argument of patentability.
- 30. Concurrent with the '645 Patent prosecution proceeding before the PTO, Plaintiff's European Patent No. 0343217, the European counterpart of the '645 Patent, was under review in an opposition proceeding before the Opposition Division of the European Patent Office ("Opposition Division"). In the European opposition proceeding, the Opposition Division considered issues and patentability arguments substantially similar to those involved in the reexamination of the '645 Patent.
- 31. A patentability argument considered in both the '645 proceeding and the European opposition proceeding was the reliability of surrogate assays in predicting the presence of stem cells in a sample of umbilical cord blood.
- On July 21, 1999, the Opposition Division revoked European Patent No. 32 0343217. The Opposition Division issued a written opinion outlining the issues and arguments of Plaintiff and the five Opponents, and explaining the reasoning of the Opposition Division in revoking the Patent ("the European revocation decision").

- 33. In the European revocation decision, explicitly rejecting Plaintiff's argument to the contrary, the Opposition Division noted "the broad consensus in the scientific community as to the reliability of surrogate assays . . . as indirect evidence for the presence of stem cells in a sample." The European revocation decision also found Plaintiff's argument in contradiction to the opinion of one of the alleged inventors, Dr. Hal E. Broxmeyer, in a 1997 article, "High-Efficiency Recovery of Immature Haematopoietic Progenitor Cells with Extensive Proliferative Capacity from Human Cord Blood Cryopreserved for 10 years," published in Clinical and Experimental Immunology ("the Broxmeyer article"). In addition, the European patent was rejected as lacking novelty in view of a prior use by Rubinstein in the mid-1980s, which was described in a declaration that Rubinstein had submitted to the Opposition Division on or about November 10, 1988.
- 34. At the time of the European revocation decision, the '645 Patent was being prosecuted before the PTO. Although the PTO was currently considering the same issue, Plaintiff failed to disclose to the PTO the Opposition Division's decision revoking European Patent No. 0343217.
- 35. Both the European revocation decision and the Broxmeyer article were material to the patentability of the '645 Patent.
- 36. Plaintiff knew about the existence of both the European revocation decision and the Broxmeyer article, knew that those documents were material to patentability, and intended to deceive the PTO by failing to disclose them.
- 37. In addition, the '645 Patent is unenforceable for inequitable conduct because Plaintiff failed to disclose to the PTO Rubinstein's prior work (which was in public use) relating to cryopreservation of cord blood before the filing date of the '645 Patent. Plaintiff knew of

Rubinstein's prior work relating to cryopreservation of cord blood and its materiality to the patentability of the '645 Patent before and during the prosecution of the '645 Patent. Plaintiff purposefully withheld such material information from the PTO with intent to deceive the PTO to obtain the issuance of the '645 Patent.

#### **Eighth Affirmative Defense** (Intervening Rights)

38. Defendants are entitled to "absolute" and "equitable" intervening rights under 35 U.S.C. §§ 252 and 307(b) precluding damages or injunctive relief for any alleged infringement of the claims of the '645 Patent or the '427 Patent, which are successors to U.S. Patent 5,004,681 (the '681 Patent), for which a Re-Examination Certificate was issued on April 11, 2000, and a Re-examination Order on August 19, 2004, to protect Cryo-Cell's investments made before the completion of the re-examination.

#### **Ninth Affirmative Defense** (Unclean Hands/Estoppel)

39. Plaintiff is barred from attaining any relief under the equitable doctrines of unclean hands and/or estoppel.

#### **Tenth Affirmative Defense** (Waiver)

40. Plaintiff's claims are barred by the doctrine of waiver.

#### **Eleventh Affirmative Defense** (Laches)

41. Plaintiff's claims are barred by the doctrine of laches.

# **Twelfth Affirmative Defense** (Res Judicata)

42. Plaintiff's claims are barred by the doctrine of res judicata.

# **Thirteenth Affirmative Defense** (Improper Venue)

Plaintiff's claims against Defendant Zafran are barred for improper venue. 43.

#### **COUNTERCLAIM**

Defendant Cryo-Cell International, Inc. alleges the following counterclaim against PharmaStem Therapeutics, Inc. and Nicholas Didier:

#### **Parties**

- 1. Counter-Claimant Cryo-Cell International, Inc. ("Cryo-Cell") is a corporation existing under the laws of the State of Delaware.
- 2. Counter-Defendant PharmaStem Therapeutics, Inc. ("PharmaStem") is a Delaware corporation with its principal place of business in the State of New York.
- 3. Counter-Defendant Nicholas Didier ("Didier") (collectively with PharmaStem, "Counter-Defendants") is an individual residing in the State of New York. Didier is the chief executive officer and president of PharmaStem. He has personally contacted obstetricians and hospitals in the State of Florida regarding PharmaStem's patents and the substance of this action.

#### **Jurisdiction and Venue**

- 4. This Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1332, 1337, and 1338 and 1367. The claims arise out of or are substantially related to, among other things, Section 43(a) of the Lanham Act.
- 5. Venue is proper in this District Court pursuant to 28 U.S.C. § 1391(b) and (c), because a substantial part of the false and misleading advertising, unfair competition, trade libel, and interference with contractual or other economic relationships complained of in this Complaint has occurred and is occurring in this judicial district, and because Counter-Claimants

and the public have suffered and continue to suffer injury in this judicial district as a result of the matters complained of herein.

### **Factual Background**

- 6. Cryo-Cell is engaged in the business of private banking of umbilical cord blood. By storing cord blood upon the birth of an infant, it is preserved as a potentially life saving asset. Cryo-Cell markets its services to expectant parents.
- 7. PharmaStem is the purported owner of U.S. Patents 5,004,681 ("the '681 Patent"), 5,192,553 ("the '553 Patent"), 6,461,645 ("the '645 Patent"), 6,569,427 ("the '427 Patent") and 6,605,275 ("the '275 Patent").
- 8. On February 2002, PharmaStem filed suit in the United States District Court for the District of Delaware against Cryo-Cell and several other companies, alleging infringement of the '681 and '553 patents, PharmaStem Therapeutics, Inc. v. ViaCell, Inc., et al., Civil Action No. 02-148-GMS ("the Delaware Action").
- 9. After a trial in October, 2003, a jury verdict was entered in favor of PharmaStem and against Cryo-Cell and the other companies in the Delaware Action finding the patents valid and infringed, and awarding damages to PharmaStem.
- 10. All parties in the Delaware Action timely filed post-trial motions, including a motion by PharmaStem for entry of a permanent injunction and motions by Cryo-Cell and the other defendants for judgment as a matter of law or for a new trial. Those motions have been fully briefed and argued, and await decision by the Delaware District Court.

#### **PharmaStem and Didier Conduct**

- 11. On or about June 1, 2004, Counter-Defendants sent to obstetricians and hospitals letters substantially in the form attached hereto as Exhibit A ("the PharmaStem Letter"). Counter-Defendants sent the PharmaStem Letter to about 25,000 obstetricians and hospitals.
- The PharmaStem Letter contains false and misleading statements, particularly, 12. and without limitation, the following:

Patent infringement occurs when a person or institution practices all or part of a patented process. In the case of umbilical cord blood collection by an Obstetrician, the Court ruled that infringement occurs even if the cryopreservation and storage is performed by a third party.

- 13. These statements are false under 15 U.S.C. § 1125(a) and constitute a deceptive and unfair trade practice because Counter-Defendants made no mention of (1) the sale or offer to sell requirement, (2) the "acting in concert or working together" requirement, or (3) that the sale of a service cannot satisfy 35 U.S.C. § 271(c).
- The Delaware District Court found that the PharmaStem Letter contained false 14. and misleading statements. On July 2, 2004, the Honorable Gregory M. Sleet entered an Order for Injunctive Relief ("Order") in response to a motion filed by Cryo-Cell and the other defendants in the Delaware Action, finding that "PharmaStem's June 1, 2004 letter to Obstetricians (the 'PharmaStem Letter') contains false and misleading statements concerning the Court's rulings to date." The Order is attached hereto as Exhibit B.
- 15. Judge Sleet particularly found that the following statement in the PharmaStem Letter was false and misleading: "Patent infringement occurs when a person or institute practices all or part of a patented process." The Order further states "[t]he Court finds this statement is misleading because it is black letter law that in order to prove contributory infringement of a

method patent, the entire patented process must be performed. By suggesting that infringement would occur when only part of a process is performed, the letter is misleading."

- 16. Judge Sleet also found that the following statement in the PharmaStem Letter was false and misleading: "In the case of umbilical cord blood collection by an obstetrician, the Court ruled that infringement occurs even if the cryopreservation and storage is performed by a third party." The Order further states
  - [T]he Court finds this statement misleading for at least the following reasons. First, the sentence states that 'the Court ruled' with respect to the 'case' of 'umbilical cord blood collection by an Obstetrician.' This Court never made any rulings regarding conduct by obstetricians. There were no such allegations advanced in the trial of this matter. Second, the sentence leaves out several important elements that must be proved to show contributory infringement. This missing elements include:
  - (1) that there must be a sale or offer to sell by the party that is accused of contributory infringement,
  - (2) that the party accused of contributory infringement must be 'acting in concert or working together' with the other parties whose combined conduct performed each and every element of the patented process, and
  - (3) that, under [35 U.S.C.] § 271(c), a sale of a service, as opposed to a sale of a tangible physical object, is not sufficient to satisfy the requirements of the contributory infringement statute.
  - The Court finds that without these elements, the statement is misleading.
- 17. Judge Sleet ordered PharmaStem not to make any further false or misleading communications to obstetricians.
- 18 Counter-Defendants, however, did not stop disseminating false and/or misleading statements after issuance of the injunction. On August 2, 2004, after Counter-Defendants filed a second patent infringement lawsuit against Cryo-Cell, Counter-Defendants disseminated a press release ("Press Release"), attached hereto as Exhibit C, that contained false and misleading

statements similar to those in the PharmaStem Letter. The Press Release makes no mention of the sale or offer to sell requirement, the "acting in concert or working together" requirement, or that the sale of a service cannot satisfy § 271(c), which was the basis for issuing the injunction on July 2, 2004.

- amnesty agreement to obstetricians ("Amnesty Agreement"), attached hereto as Exhibit D, that contained false and misleading statements similar to those in the PharmaStem Letter and Press Release. Counter-Defendants insisted that the obstetricians sign the Amnesty Agreement to avoid legal action by Counter-Defendants, and the obstetricians work only with Counter-Defendants' licensees. Indeed, in disregard of the findings and final orders of the Delaware District Court, the letter of August 20, 2004, states the following: "It is PharmaStem's position, as asserted in the recent lawsuits, that obstetricians are liable for patent infringement if they collect cord blood or market services for unlicensed cord blood banks."
- 20. The press release of August 2, 2004, and the letter of August 20. 2004, were published after Counter-Defendants had already made misrepresentations by the earlier letters of June, 2004, and, as such and as a matter of fact and in the eyes of obstetricians and the public, served to confirm and bolster the misrepresentations, and to confirm and bolster the misplaced and inaccurate position, of CounterDefendants. The press release and letter failed to correct the earlier misrepresentations, failed to disclose the inaccuracy of the earlier misrepresentations, and failed to disclose the rulings of the Delaware District Court.
- 21. Under no proper interpretation of the PharmaStem Patents could an obstetrician be liable for patent infringement based on collecting umbilical cord blood at the time of a delivery and providing it to the patient for the patient's shipment of the blood to a bank.

Counter-Defendants' threat of such improper enforcement of the patents constitutes misuse of the PharmaStem Patents.

- 22. Further, Counter-Defendants have sponsored links at such Internet sites as Google.com and Yahoo.com in which Counter-Defendants identify Cryo-Cell and claim it is an "unlicensed bank," without direct reference to Counter-Defendants' purported patents, and even though Cryo-Cell holds all required state licenses, including licenses from the states of New York and New Jersey to operate cord blood banking services. The sponsored links further state, "Why Take a Risk?" Such unauthorized use of Cryo-Cell's trademark, and implication that Cryo-Cell's services are not licensed, for example, by state health departments, constitute disparagement and deceptive trade practices.
- 23. Counter-Defendants issued these and further statements in bad faith to create a false implication with the consuming public as alleged herein. The allegations in the counterclaims are, based on information and belief, representative of conduct by PharmaStem and Didier and not exclusive.
- 24 The PharmaStem Letter, Amnesty Agreement and Internet sites have had their intended damaging effect on Cryo-Cell. Physicians have refused to collect cord blood and patients have been prevented from using Cryo-Cell's services.
- 25. Counter-Defendants have acted with the purpose of injuring Cryo-Cell in its business and property.

# FIRST CLAIM FOR RELIEF (Interference With Contractual and Business Relationships)

- 26. Counter-Claimant incorporates by reference as if fully set forth herein Paragraphs 1 through 25.
- 27. The aforesaid conduct of Counter-Defendants has had the effect of interfering by wrongful means with Cryo-Cell's contractual or other economic relationships with persons who desire, or who may desire, to purchase its services of cryopreservation and storage of umbilical cord blood. Counter-Defendants' conduct was undertaken to harm Cryo-Cell.
- 28. In fact, the aforesaid conduct of Counter-Defendants has tortiously interfered with Cryo-Cell's contractual and business relationships with parents who were purchasing Cryo-cell's services of cryopreservation and storage of their children's umbilical cord blood by causing the parent's obstetrician and medical care providers to refuse to collect the umbilical cord blood.
- 29. The aforesaid conduct of Counter-Defendants has tortiously interfered with Cryo-Cell's contractual and business relationships with obstetricians and medical care providers who agreed to collect umbilical cord blood to be cryopreserved and stored by Cryo-Cell, but then revoked such agreement because of the tortious interference of Counter-Defendants.
- 30. As a result of Counter-Defendants' unprivileged and unjustified interference with Cryo-Cell's contractual or other economic relationships, Cryo-Cell has suffered damages, *inter alia*, in the form of lost profits on services they would have performed but for Counter-Defendants' interference.
- 31. Unless Counter-Defendants are enjoined and restrained from continuing their unlawful conduct, Cryo-Cell will continue to suffer damage in its business or property by reason of such tortious interference.

32. Counter-Defendants' conduct has been extreme and outrageous, entitling Cryo-Cell to punitive damages.

WHEREFORE, Defendants and Counter-Claimant pray for judgment as follows:

- A. For an award of compensatory damages to Defendants and Counter-Claimant in an amount to be proven at trial;
  - B. For an award of punitive damages;
- C. For pre- and post-judgment interest on the entire amount of Counter-Claimant's award, including its costs, at the highest rate permitted by law;
- D. For an injunction, both preliminary during the pendency of the action and permanent, prohibiting Counter-Defendants from tortiously interfering with Cryo-Cell's contractual and business relationships; and
- E. For an award of Defendants and Counter-Claimant' costs, including attorneys' fees, incurred in connection with this litigation; and
  - F. For such other and further relief as this Court deems just and proper.

# SECOND CLAIM FOR RELIEF (Lanham Act § 43(a))

- 33. Cryo-Cell incorporates by reference as if fully set forth herein Paragraphs 1 through 25.
- 34. Counter-Defendants have sent advertisements and promotions into interstate commerce via mail, the Internet and other means in which it makes false and misleading statements to the public, physicians, and health care organizations, and to actual and potential users of Cryo-Cell services to take business away from Cryo-Cell and get those actual or potential users to do business with PharmaStem's licensees.

- 35. The deception is material, and has influenced, and will continue to influence, the purchasing decisions of potential and actual users of Cryo-Cell's services.
- 36. The deceptive statements were disseminated to numerous physicians and actual and potential users of Cryo-Cell's services throughout the United States, and were thereby placed into interstate commerce.
- 37. Cryo-Cell has been and will continue to be injured as a result of these statements, either by direct diversion of its sales to others or by a lessening of goodwill associated with Cryo-Cell's services.
- 38. The deceptive advertisement violates § 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125(a), which prohibits Counter-Defendants from using false, misleading, or disparaging representations of fact that misrepresent the nature, characteristics, or qualities of Cryo-Cell's goods, services, or commercial activities.
- 39. Counter-Defendants' conduct has caused and/or is likely to cause damage to Cryo-Cell in an amount to be determined at trial, and unless restrained, will cause further damage to Cryo-Cell.

WHEREFORE, Defendants and Counter-Claimant pray for judgment as follows:

- A. For an award of compensatory damages to Defendants and Counter-Claimant in an amount to be proven at trial and that such award be trebled to an amount of three times the compensatory damages;
- B. For an award of Defendants and Counter-Claimant' costs, including attorneys' fees, incurred in connection with this litigation;

- C. For pre- and post-judgment interest on the entire amount of Counter-Claimant's award, including its costs, at the highest rate permitted by law; and for such other and further relief as this Court deems just and proper; and
- D. For an injunction, both preliminary during the pendency of the action and permanent, prohibiting Counter-Defendants from which prohibits Counter-Defendants from using false, misleading, or disparaging representations of fact that misrepresent the nature. characteristics, or qualities of Cryo-Cell's goods, services, or commercial activities;
  - E. For such other and further relief as this Court deems just and proper.

# THIRD CLAIM FOR RELIEF (Patent Misuse)

- Cryo-Cell incorporates by reference as if fully set forth herein Paragraphs 1 40. through 25.
- 41. Counter-Defendants' enforcement, and attempts to enforce, the '645 Patent, the '427 Patent and '275 Patent against Zafran and other physicians through accusations of infringement and the filing of patent infringement suits upon patent claims that they know are of a scope that does not cover accused products, processes, or activities, and in particular does not cover the collection of umbilical cord blood, constitutes patent misuse.
- 42 Counter-Defendants' have misused the '645 Patent, the '427 Patent and '275 Patent by asserting these patents against Zafran and other physicians in a manner that attempts to impermissibly broaden the scope of the patent grants, in particular to cover the collection of umbilical cord blood, in order to preclude, hamper, hinder and delay Cryo-Cell from selling its processes and services. Upon information and belief, Counter-Defendants' current use of its patents in this manner, attempting to block Cryo-Cell from competing fairly in the market, constitutes a knowing, anticompetitive misuse of these patents.

- 43. Cryo-Cell has been and will continue to be injured as a result of Counter-Defendants' patent misuse, either by direct diversion of its sales to others or by a lessening of goodwill associated with Cryo-Cell's services.
- 44. As a result of Counter-Defendants' misuse, the '645 Patent and the '427 Patent are unenforceable and cannot be enforced against Cryo-Cell.

WHEREFORE, Defendants and Counter-Claimant pray for judgment as follows:

- A. That Plaintiff take nothing for each and every cause of action averred in the Complaint;
- B. That judgment on the Complaint, and each and every claim for relief therein, be entered in favor of Defendants and Counter-Claimants, and against Plaintiff;
- C. Declaratory judgment that Counter Defendants have misused the patents, which are thus unenforceable.
- D. For an award of Defendants and Counter-Claimant' costs, including attorneys' fees, incurred in connection with this litigation; and
  - E. For further relief as this Court deems just and proper.

# **FOURTH CLAIM FOR RELIEF** (Deceptive and Unfair Trade Practices)

- 45. Cryo-Cell incorporates by reference as if fully set forth herein Paragraphs 1 through 25.
- 46. Counter-Defendants' advertising, as alleged above, constitute deceptive and unfair trade practices and has caused and/or is likely to cause damage to Counter-Claimants and to the public in an amount to be determined at trial, and, unless restrained, will further damage Cryo-Cell and the public.

WHEREFORE, Defendants and Counter-Claimant pray for judgment as follows:

- A. For an award of compensatory damages to Defendants and Counter-Claimant in an amount to be proven at trial;
- B. For an award of Defendants and Counter-Claimant' costs, including attorneys' fees, incurred in connection with this litigation; and
- C. For pre- and post-judgment interest on the entire amount of Counter-Claimant's award, including its costs, at the highest rate permitted by law; and
  - D. For such other and further relief as this Court deems just and proper.

#### **DEMAND FOR JURY TRIAL**

Defendants/Counter-Claimants demand trial by jury of all issues so triable.

Dated: September 17, 2004.

Respectfully submitted,

AKERMAN SENTERFITT

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Attorneys for Cryo-Cell International, Inc. and Brian Zafran, M.D.

#### **CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on September 17th, 2004, I electronically filed the foregoing Defendants' Joint Answer and Counterclaim with Exhibits A through D with the Clerk of the Court which will send a notice of electronic filing to Charles A. Carlson, Esq., Barnett, Bolt, et al., Post Office Box 3287, Tampa, Florida 33601. I further certify that I sent by U.S. Mail the foregoing document and notice of electronic filing to Paul Andre, Esq., and Lisa Kobialka, Esq., Perkins Coie LLP, 101 Jefferson Drive, Menlo Park, CA 94025; and Charles A. Carlson, Esq., Barnett, Bolt, et al, P.O. Box 3287, Tampa, FL 33601.

/s/ Charles F. Ketchey, Jr.